

### **Remarks**

Claims 1-15 and 44-47 are presently pending in the application. All claims stand rejected. Claim 1 has been amended. Claims 2-15 and 44-47 have been withdrawn from consideration, without prejudice. Claim 1 is hereby submitted for review and reconsideration.

### **Claim Rejections Under 35 § U.S.C. 103**

Claims 1 stands rejected under 35 § U.S.C. 103 as obvious over Paul et al. (US Patent No. 5,292,538, "Paul") in combination with Riley (U.S. Patent No. 5,976,568). This rejection is respectfully traversed.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (See MPEP 2143.)

The present invention is a food supplement which comprises  $\alpha$ -lipoic acid or a derivative thereof, and at least one ingredient selected from the group consisting of amino acids and derivatives thereof and sources of amino acids, in amounts effective to increase lean muscle mass and strength wherein the  $\alpha$ -lipoic acid or the  $\alpha$ -lipoic acid derivative is from about 2 mg per gram of food supplement.

It is hypothesized that insulin is a primary factor that stimulates the uptake of glucose and amino acids into muscle cells. The lipoic acid, at the claimed level, both

mimics and enhances the actions of insulin in glucose and amino acid transport into muscle cells thereby increasing lean muscle mass.

The claims have been rejected because allegedly it would be obvious to combine the teachings of Paul with those of Riley. Paul teaches an amino acid complex which may contain lipoic acid. Paul does not teach the range of lipoic acid recited in the claims. Riley teaches a nutritional supplement comprising from 0 to 750 mg of alpha lipoic acid. The lipoic acid range in Riley overlaps with the lipoic acid range recited in the claim. Thus, the Examiner alleges that it would have been obvious to one of skill in the art to employ the lipoic acid range disclosed by Riley in the nutritional supplement of Paul to arrive at the invention of the claims.

Applicants maintain that there is no suggestion or motivation to modify Paul in view of Riley, or to combine the teachings of Paul and Riley, to arrived at the claimed invention. Rather, the Applicants believe that the conclusion of obviousness is based on impermissible hindsight reasoning.

Paul is directed towards a composition, which provides for sustained energy and nutrition to support an anabolic physiological state in humans. The composition of Paul provides for lipoic acid as an anti-oxidant. There is no suggestion in Paul that lipoic acid is effective to increase muscle mass and strength at the levels recited in the claims, or at any levels. The concentration of lipoic acid disclosed in Paul is below the level recited in the claims because Paul only contemplates the use of lipoic acid as an antioxidant.

Riley also discloses lipoic acid as an anti-oxidant. Riley does not disclose amino acids. There is no suggestion in Riley that lipoic acid may be administered in a composition with amino acids to promote building lean muscle mass.

Nor is there any suggestion or motivation generally available to one of ordinary skill in the art, to administer lipoic acid, at the levels claimed, in combination with a source of amino acids, to build lean muscle.

Consequently, the Applicants maintain that the Paul and Riley do not render the claims prima facie obvious because one of skill in the art would have no reason to combine Paul and Riley to build lean muscle.

**Conclusion**

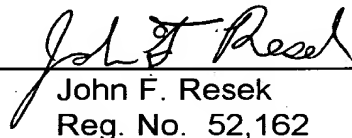
In view of the foregoing remarks, it is believed that the present application is in condition for allowance, which action is earnestly solicited.

The Examiner is invited, after consideration of the present response, to contact the undersigned to discuss any issue in this case that would expedite allowance of the subject application.

Respectfully Submitted,

KENYON & KENYON

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